



UNITED STATES PATENT AND TRADEMARK OFFICE

47

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,158	01/04/2005	Holger Klapproth	STURK0017	9557

24203 7590 08/23/2006

GRIFFIN & SZIPL, PC
SUITE PH-1
2300 NINTH STREET, SOUTH
ARLINGTON, VA 22204

EXAMINER

BRADLEY, CHRISTINA

ART UNIT	PAPER NUMBER
----------	--------------

1654

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/520,158	KLAPPROTH, HOLGER	
	Examiner	Art Unit	
	Christina Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14,16-22,24-28 and 30-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14,16-22,24-28 and 30-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>07/28/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the species trehalose and SEQ ID NO: 2 in the reply filed on 07/28/2006 is acknowledged. Claims 1-14, 16-22, 24-28 and 30-37 are pending; claims 15, 23 and 29 are cancelled.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7, 22 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "ready-to-use solution" is not defined in the claim or specification rendering the composition indefinite.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-14, 16-22, 24-28 and 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen *et al.* (*J. Biotech.*, 1999, 72, 115) in view of Browne *et al.* (*Nature*, 2002, 416, 38). Nguyen *et al.* teach a process for stabilizing immobilized antibodies by applying

Art Unit: 1654

a solution of a protein, 0.1% BSA, and a non-reducing disaccharide, 5% trehalose (see Figure 1).

The antibodies taught by Nguyen *et al.* are immobilized on polystyrene microtitration plates and are intended for use in an ELISA assay which is analytical and/or diagnostic. Nguyen *et al.* do not teach the use of an LEA class protein in the stabilizing solution. Browne *et al.* teach the LEA class proteins comprising the sequence motifs KTAEFRDSAGE (SEQ ID NO: 2),

KGQEFKERAGE (SEQ ID NO:3), KAEETKQRAGE (SEQ ID NO: 4), KMDETKQRAGE

(SEQ ID NO: 5), KARKTKDSAAE (SEQ ID NO:6), KAKEYKDYTAE (SEQ ID NO:7),

KARETTEKARE (SEQ ID NO: 8), and TKDSAAEKARE (SEQ ID NO: 9) and corresponding

to GenBank accession numbers AF4230 and S39475 (see Figure 1c). Browne *et al.* teach that

trehalose protects membranes and proteins from desiccation damage in anhydrobiotic organisms.

Browne *et al.* further teach that “non-reducing sugars and LEA protein act synergistically to promote the formation of a stable ‘bioglass’ in the cytoplasm of anhydrobiotic plants and

desiccation-tolerant seeds and pollen” and that “the bioglass may trap fragile biological

molecules in time and space and preserve them from desiccation damage”.

6. It would have been obvious to one of ordinary skill in the art to substitute the LEA class proteins comprising SEQ ID NOs: 2-9 and/or GenBank accession numbers AF423069 and S39475 taught by Browne *et al.* for the BSA in the protein stabilizing composition taught by Nguyen *et al.*, and to use the composition in a process to stabilize protein immobilized on an analytical or diagnostic device such as a polystyrene microtiter well or in a process to produce a surface with immobilized and stabilized biomolecules as taught by Nguyen *et al.* In doing so, all limitations for the composition (claims 1-7), the surface covered with an immobilized and stabilized biomolecule (claims 10-14, 25, 27, 28, 30-37), the process for stabilizing protein

Art Unit: 1654

(claims 8, 9, 16-22), the process for the production of a surface covered with an immobilized and stabilized biomolecule (claim 24) and the component of an analytic or diagnostic device (claim 26) will be met. The skilled artisan would have been motivated to do so given that Browne *et al.* state that LEA proteins and non-reducing sugars work synergistically in certain organisms to stabilize and preserve proteins and other biomolecules in desiccation conditions. There would have been a reasonable expectation of success given that Nguyen *et al.* already employed a protein in their stabilizing solution, BSA, along with trehalose. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.


Conclusion

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.
9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1654

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cmb


Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600